

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

DeGRADO *et al.*

Application No.: 10/801,951

Filed: March 17, 2004

For: **Facially Amphiphilic Polymers and
Oligomers and Uses Thereof**

Confirmation No.: 2895

Art Unit: 1627

Examiner: CHONG, Yong Soo

Atty. Docket: 1694.0630003/JMC/M-R/KHR

Reply Brief Under 37 C.F.R. § 41.41

Mail Stop Appeal Brief - Patents

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants filed a Brief on Appeal to the Board of Patent Appeals and Interferences for the above-captioned application on September 23, 2009. The appeal is directed to the final rejection of claims 16-48 and 67-73 under the judicially created doctrine of obviousness-type double patenting as allegedly being obvious over claims 1, 4-8, 11, 14-15, 20-22, and 26 of U.S. Patent No. 7,173,102 B2 ("the '102 patent"), as set forth in the Final Office Action mailed February 2, 2009. The Examiner's Answer was mailed December 8, 2009. In reply to the Examiner's Answer, Appellants submit this Reply Brief under 37 C.F.R. § 41.41.

I. Arguments

This Reply Brief addresses the points raised by the Examiner in Section 10, "Response to Argument," of the Examiner's Answer. The Examiner's "Grounds of Rejection" in Section 9 of the Examiner's Answer reflects the previous Final Office Action dated January 7, 2009, and has been addressed in the previously filed Brief on Appeal.

A. Pending Claims 16-48 and 67-73 are Directed to a Method of Treating a Microbial Infection in an Animal, which is Not an Obvious Variant of Claim 26 of U.S. Patent No. 7,173,102 B2 which Requires Providing a Substrate

The first step of an obviousness-type double patenting rejection is construing the claims being examined, as well as the claims of the prior art. *See Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968, 58 U.S.P.Q.2d 1869, 1878 (Fed. Cir. 2001); MPEP § 804, p. 800-22.

Pending independent claims 16, 17, and 67 are directed to a *method of treating a microbial infection in an animal in need thereof* comprising administering an effective amount of a pharmaceutical composition comprising a pharmaceutically acceptable carrier or diluent and an amphiphilic oligomer of general Formula II: $R^1-[-x-A_1-x-y-A_2-y]_m-R^2$ wherein m is 1 to about 20 (claim 16), 1 to about 10 (claim 17) or 1, 2, or 3 (claim 67). Claims 18-48 and 69-73 depend directly or indirectly from claim 16 and further define R^1 , x, A_1 , y, A_2 , R^2 , or the type of microbial infection. Claim 68 depends from claim 67 and specifies the specific compounds to be administered.

In comparison, claim 26 of the '102 patent is generally directed to a method of killing microorganisms comprising providing a substrate having disposed thereon a contact killing,

facially amphiphilic polymer or oligomer of claim 1, claim 14, or claim 20; and placing the facially amphiphilic polymer or oligomer on the substrate in contact with a microorganism to allow formation of pores in the cell wall of the microorganism. Exhibit 1, col. 45, ll. 14.

1. Pending Claims 16-48 and 67-73 are Directed to a Method of Treating a Microbial Infection in an Animal, which is Not an Obvious Variant of the '102 Patent

The Examiner asserted in the Examiner's Answer that "Appellant is reminded that terms in the claims must be given its *broadest* reasonable interpretation that is consistent with the specification." (Examiner's Answer, page 6 (emphasis added)). However, the Examiner is incorrect that the claims of an issued patent are to be construed broadly. Instead, the term of an issued patent must be given its plain meaning unless the plain meaning is inconsistent with the specification, *i.e.*, the "ordinary and customary meaning" given to the term by those of ordinary skill in the art. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313, 75 U.S.P.2d 1321, 1326 (Fed. Cir. 2005) (*en banc*).

The '102 patent disclosure, taken as a whole, indicates that the term "substrate" was intended to encompass only inanimate surfaces, such as wood, synthetic polymers, paper, rubber, and glass, and not living tissues. *See e.g.*, Exhibit 1, col. 26, lines 47-6; col. 27, lines 5-6; and col. 45, lines 23-31. Nowhere in the '102 patent disclosure is there any information regarding administration of the claimed polymers and oligomers to animals, much less to an animal in need to treatment of a microbial infection.

The Examiner asserts that the '102 patent "teaches that the scope of the term 'substrates' broadly includes any object that is exposed to or susceptible to bacterial or microbial contamination can be treated with the disclosed oligomers." (Examiner's Answer,

page 5.) The Examiner indicates that his overly broad construction of "substrate" in the claim 26 of the '102 patent is based upon the fact that "testing of the bacterial efficacy has been performed in mammals with these polymers in water (col. 24, lines 57-64, example 5-6)." (*Id.*) Additionally, according to the Examiner, the '102 patent

teaches a need to design these polymers with reduced toxicity to birds, fish, mammals, and other higher organisms. Furthermore, any object that is exposed to or susceptible to bacterial or microbial contamination can be treated with these polymers, particularly in food and health care, for example for the use in contact lenses. Both pets and agronomic animals are exposed to and harbor a variety of infectious pathogenic organisms that can cause disease in animals or humans (col. 27, lines 1-28).

(*Id.* pages 5-6.)

The sections the Examiner cites in the '102 patent have been taken out of context. These passages only indicate that the disclosed polymers and oligomers should be tested for toxicity in case the polymers and oligomers leach from the substrate surfaces to which they're applied. According to Dr. David P. Nicolau, Pharm.D., FCCP, an expert in the infectious disease field, "[n]ew antibacterial materials to be employed as surface coatings need to act as antibacterial agents while not having adverse consequences to the surrounding environment Because the polymers may eventually leach from the object, the [U.S. Environmental Protection Agency] may require a showing the polymers are not toxic to humans." Exhibit 3, p. 5, ¶ 10 (citing "Guidelines for Exposure Assessment," Risk Assessment Forum, U.S. Environmental Protection Agency (May 1992), pages 2 & 5 (provided as Exhibit A2 to the Declaration)).

Also, the '102 patent disclosure of "[b]oth pets and agronomic animals are exposed to and harbor a variety of infectious pathogenic organisms that can cause disease in animals or

humans," does not support the Examiner's contention that "substrate" of claim 26 of the '102 patent encompasses administration of the claimed polymers and oligomers to animals. Rather, when read in context, the entire passage indicates that polymers and oligomers are to be applied to inanimate surfaces to prevent the spread of bacteria or microbial contamination to these inanimate surfaces by pets and agronomic animals.

Therefore, despite the Examiner's assertion, a person of ordinary skill in the art would not reasonable interpret the term "substrate", in view of the plain language of claim 26 and the '102 patent specification, to broadly encompass living organisms. As such, the Examiner's construction of the term "substrate" of claim 26 of the '102 patent is wrong.

Because the Examiner erred in broadly construing the term "substrate" of claim 26 of the '102 patent, there is no basis to support the Examiner's contention that pending claims 16-48 and 67-73 are obvious variants of the asserted claims of the '102 patent.

B. The Examiner has Not Shown Why Administering Shorter Oligomers to Treat a Microbial Infection in an Animal is Prima Facie Obvious

As described above, the pending claims require 1 to about 20 (claims 16, 18-48, and 69-73), 1 to about 10 (claim 17), or 1, 2, or 3 (claims 67 and 68) monomer subunits. Although there is some overlap in the structural formulas of pending claims 16-48 and 67-73 and claim 26 of the '102 patent, that overlap is insufficient for the Examiner to establish a *prima facie* case of obviousness to satisfy the requirements of judicially created doctrine of obviousness-type double patenting. See MPEP § 2144.08, pp. 2100-154-53 (citing *In re Baird*, 16 F.3d 380, 382, 29 U.S.P.Q.2d 1550, 1552 (Fed. Cir. 1994))("The fact that a claimed species of subgenus is encompassed by a prior art genus is not sufficient by itself to

establish a *prima facie* case of obviousness." In the Examiner's Answer, the Examiner indicated that the '102 patent "teach[es] a narrower subgenus of 2 to about 30 monomer units in dependent claims such as claim 2." (Examiner's Answer, page 7.) The number of monomer units recited in the pending claims and the claims of the '102 patent are not ranges, such that where the claimed ranges overlap, a *prima facie* case of obviousness exists. Rather, the monomer units recited in the claims indicate how long the oligomers to be administered may be. As such, the oligomers to be administered in the methods of the pending claims is a subgenus of a genus disclosed in the '102 patent. Therefore, under *In re Baird*, the fact that there is still overlap between the structural formulas of the pending claims and claim 2 of the '102 patent is insufficient to establish a *prima facie* case of obviousness. The Examiner simply stated that a narrower genus is *prima facie* obvious is insufficient.

Additionally, the Examiner argued that "in polymer science, one of ordinary skill in the art knows that when multiple repeat monomer units are present or as one increases the number of monomer units, the polymer behaves very similarly in terms of physical and chemical properties, no matter what the number of monomer units is." (Examiner's Answer, page 8.) This statement is incorrect for several reasons.

First, the pending claims are directed to methods of treatment, not compounds. The issue is not whether the oligomers of the pending claims are obvious over the polymers and oligomers of the '102 patent claims. Rather, the question is whether a method of treating a microbial infection in an animal in need thereof comprising administering an oligomer with 1 to about 20 monomer subunits is obvious in view of a method of killing microorganisms

comprising providing a facially amphiphilic polymer or oligomer with 2 to at least 30 monomer subunits (or as many as 500 monomer subunits). As such, the Examiner's characterization of the field as "polymer science" is incorrect. A person of ordinary skill, as well as the person of ordinary's skill reasonable expectation of success, will differ between the fields. Therefore, the Examiner has misconstrued the field of art relevant to the obviousness analysis. Because the Examiner has selected the selected the wrong person of ordinary skill in the art, as well as the incorrect field, the Examiner has incorrectly applied the facts to the obviousness analysis. As such, the Examiner's rejection that the currently pending claims 16-48 and 67-73 are obvious variants of claims 1, 4-8, 11, 14-15, 20-22, and 26 of the '102 patent is incorrect.

Second, the Examiner provided no evidence for his assertion that polymers of different sizes have similar chemical and physical properties. If the Examiner is taking official notice of a fact that is asserted to be common knowledge, "the basis for such reasoning must be set forth explicitly." MPEP § 2144.08, p. 2100-146. Additionally, "the examiner must provide specific factual findings predicated on sound technical and scientific reasoning to support his or her conclusion of common knowledge." *Id.* (citing *In re Soli*, 317 F.2d 941, 946, 137 U.S.P.Q. 797, 801 (C.C.P.A. 1963) and *In re Chevenard*, 139 F.2d 711, 713, 60 U.S.P.Q. 239, 241 (C.C.P.A. 1943)). The Examiner did not state he was taking official notice regarding polymer properties. Additionally, the Examiner did not provide specific factual findings based upon sound scientific knowledge.

Instead, the Examiner incorrectly stated that polymers of different sizes have similar physical and chemical properties. Rather, polymers of different sizes do have different

chemical and physical properties. The '102 patent specification illustrates that polymers of different lengths have different properties. Specifically, the '102 patent recites that "[f]acially amphiphilic molecules with molecular weights of about 0.8 kD to about 20 kD will be more prone to leach from the surface of the substrate." Exhibit 1, col. 5, lines 56-58. Therefore, the '102 patent demonstrate that shorter polymers have different properties than longer polymers. As such, the Examiner's assertion that polymers with repeat units in the teens and twenties are obvious over longer polymers is factually and scientifically incorrect.

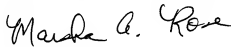
Accordingly, for these additional reasons, there is no basis to support the Examiner's rejection that pending claims 16-48 and 67-73 are obvious variants of the asserted claims of the '102 patent.

II. Conclusion

In light of the arguments above, as well as those set forth in Appellants' Brief on Appeal filed September 23, 2009. Appellants respectfully submit that the rejection of claims 16-48 and 67-73 under the judicially created doctrine of obviousness-type double patenting as allegedly being obvious over claims 1, 4-8, 11, 14-15, 20-22, and 26 of the '102 patent is improper and should be reversed.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in cursive script that reads "Marsha A. Rose".

Marsha A. Rose
Attorney for Appellants
Registration No. 58,403

Date: 2/5/2010

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

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